)			OIPE	NC 58	*	
Form PTC)/SB/08A	10	All II . A description	البيا (mplete if Known	
l		\ <u>E</u>		Application Number	10/051,853	
INFOR	MATION	DISCLE	SURE	First Named Invent	January 17, 2002	
STATE	MENTB	Y APPLI	CAMPEN	First Named Invent r	Alan E. Kligerman et al.	
(1100.0				Group Art Unit	1616	
(use a	s many she	ets as net	æssary)	Examiner Name	Not Yet Assigned	
Sheet	1	of	6	Attorney Docket Number	7706-232U1	

U.S. PATENT DOCUMENTS					
Exr Initials	U.S. Patent Document		Name of Inventor or Applicant of Cited Document	Date of Publication of	
	Number	Kind Code (if known)		Cited Document MM-YYYY	
500	2,036,345		Merkel	04-1936	
1	3,061,442		Ward et al.	10-1962	
	3,952,092	***	Bowen et al.	04-1976	
	4,206,209		Kracauer et al.	06-1980	
	4,689,218		Gazzaniga et al.	08-1987	
	4,740,380		Melachouris et al.	04-1988	
	4,826,675		Gaffar et al.	05-1989	
	4,834,966		Gazzaniga et al.	05-1989	
	4,935,227		Duckworth	06-1990	
	4,980,153		Jackson et al.	12-1990	
	5,015,465		Straw	05-1991	
	5,026,539		Jackson et al.	06-1991	
	5,087,444		Jackson et al.	02-1992	
	5,112,600		Jackson et al.	05-1992	
	5,202,145		Wisler et al.	04-1993	
	5,227,154		Reynolds	07-1993	
	5,310,542		Au et al.	05-1994	
	5,362,480		Au et al.	11-1994	
	5,378,131		Greenberg	01-1995	
	5,389,371		Shiao	02-1995	
	5,409,902		Carson et al.	04-1995	
	5,416,075		Carson et al.	05-1995	
	5,447,732		Tanimoto et al.	09-1995	
	5,449,509		Jackson et al.	09-1995	
	5,490,978		Spaltro et al.	02-1996	
	5,571,502		Winston et al.	11-1996	
	5,603,922		Winston et al.	02-1997	
	5,605,675		Usen et al.	02-1997	
	5,614,175		Winston et al.	03-1997	
	5,665,415		Kligerman et al.	09-1997	
	5,672,351		Chikindas et al.	09-1997	
	5,747,004		Giani et al.	05-1998	
	5,801,226		Cummins et al.	09-1998	
	5,817,296		Winston et al.	10-1998	
	5,827,505		Hughes et al.	10-1998	
	5,833,954		Chow et al.	11-1998	
	5,833,957		Winston et al.	11-1998	
	5,840,322		Weiss et al.	11-1998	
(5,866,102		Winston et al.	02-1999	
	5,869,119		Kligerman et al.	02-1999	
Ew-	5,972,321	1	Kligerman et al.	10-1999	

Examiner	6.1	Date Considered /b//p/p7
Signature	910-0	Considered / V / V V V

	(1 6 4005						
Form PTC	D/SB/08A	Alk 1	Ü			C mplete if Kn wn		
	•		Expplic	ati n Numb		10/051,853		
INFOR	MATION DIS	CKOSURE, AP	Filing	Filing Date January 17, 2002				
STATE	MENT BY A	First N	lamed Inve	nt r	Alan E. Kligerman et al.			
			Group	Art Unit		1616		
(use a	s many sheets a	as necessary)	Exami	ner Name		Not Yet Assigned		
Sheet	2 of	6	Attorn	ey Docket I	Number	7706-232U1		
	FOREIGN PATENT DOCUMENTS							
		Foreign Patent	Document	t			Date of	T ₁
Exr Initial	S Country Code	Number		Kind Code (if known)	Name of	Inventor or Applicant of Cited Document	Publication of Cited Document MM-YYYY	
90	RU	523687				Viktorova et al.	05-1976	X
	FR	2 667 76		A1		_aboratories Miva	04-1992	
	EP	0 241 81		A2		Kao Corporation	10-1987	X
	EP	0 605 75		A1		jinomoto Co., Inc.	07-1994	ļ
	EP	0 865 73	37	A2	Socie	te Des Produits Nestle S.A.	09-1998	
	EP	0 941 67	71	A2	Int	ernational Flavors & Fragrances Inc.	09-1999	
	wo	97/0466	31	A1		AkPharma, Inc.	02-1997	X
	WO	97/3060		A1	Smit	hKline Beecham PLC	08-1997	X
	wo	99/0855		A1	Smit	hKline Beecham PLC	02-1999	X
	JP	10-1689	90	Α	*	Shiseido Co. Ltd.	01-1989	X
	JP	57-0436	60			* Yamada Shogo	03-1982	X
	JP	74-017587		В	* Ca	pis Food Industry Co.	05-1974	Х
Liv	JP	2000 270	810	Α		*Sunstar, Inc.	10-2000	X
* Abstra	act Only							
		OTHER	PRIOR A	RT - NON PAT	ENT LITE	RATURE DOCUMENTS		
Exr Initials	magazine, jour	of first Author (in C rnal, serial, sympo: ıblisher and city ar	sium, cata	log, etc.), volun	ne-issue nu	e (where appropriate), title of the mber(s), page(s), date (in paren	e item (book, theses). If a book,	T ₁
1-A-1	BROOK et a	d., "Calcium Gly	ceropho	sphate and De	ental Plaqu	ie," Caries Res., 9:156-162 ((1975);	1
VAI	BOWEN, "T (1972);	he Cariostatic E	ffect of C	Calcium Glyco	edrophosp	hate in Monkeys," Caries Re	es., 6:43-51	
WA.3						um Glycerophosphate on the nt. Res., 59(1):23-28 (Januar		
VAY	U BORN, "Super Solutions for Tooth Decay," The Saturday Evening Post, pp. 16, 17 (Jan./Feb. 1987);							
1~A-	NORDBÖ et al., "Desorption of Salivary Proteins from Hydroxyapatite by Phytic Acid and Glycerophosphate and the Plaque-Inhibiting Effect of the Two Compounds in Vivo," J. Dent. Res., 51(3):800, 802 (May - June 1972);							
~ A6	O-T-Cs - Ora	al Care, "Mouth	wash Are	ena In Need o	f a Boost,'	Chain Drug Review, p. 34 ((January 4, 1999);	<u> </u>
WA7	DODDS et a Retention Af (1988 May)	d., "The Relation fter Ingestion of Abstract Only:	nship Bet Several I	ween Plaque Reference Foo	pH, Plaqu ods By Hu	e Acid Anion Profiles, and C man Subjects," <i>J. Dent Res</i> ,	Oral Carbohydrate 67(5):861-5	
NAR	KALFAS et al., Effect of pH On Acid Production From Sorbitol In Washed Cell Suspensions of Oral Bacteria," Caries Res, 24(2):107-12 (1990) - Abstract Only;							

Examiner Signature Date Considered 10/	10/0)	
--	-------	--

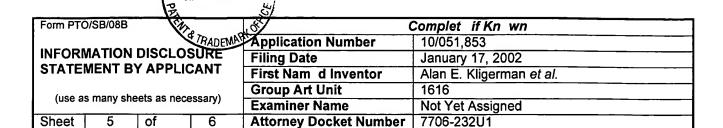
DODDS et al., "Effects of Dietary Sucrose Levels on pH Fall and Acid-Anion Profile in Human Dental Plaque After a Starch Mouth-Rinse," Arch Oral Biol, 31(8):509-12 (1986) - Abstract Only;

Form PT	O/SB/08A		Complete if Kn wn			
	MATION DISCHARE	Applicati n Number	10/051,853			
	MIX HOLD BIOCECOUNE	Filing Date	January 17, 2002			
SIAIE	MENT BY APPLICANT	First Named Inventor	Alan E. Kligerman et al			
/use	as many sheets as necessary)	Group Art Unit	1616			
	as many sneets as necessary)	Examiner Name	Not Yet Assigned			
Sheet	3 of 6	Attorney Docket Number				
F-1		PRIOR ART - NON PATENT LITER				
Exr Initials		sium, catalog, etc.), volume-issue nur	e (where appropriate), title of the item (book, mber(s), page(s), date (in parentheses). If a book,			
SWBI	SCHROEDER et al., "Dental 1995) – Abstract Only;	Erosion and Acid Reflux Diseas	se," Ann Intern Med, 122(11):809-15 (June 1,			
Br	LINGSTROM et al., "Effect of Demineralization and on Place	of Frequent Consumption of Starue pH in Situ," <i>J Dent Res</i> , 73(3	rchy Food Items on Enamel and Dentin):652-60 (Mar. 1994) - Abstract Only;			
13:	MacPHERSON et al., "An in Containing Chewing Gums of Abstract Only;	Vitro Stimulation of the Effects n pH Changes in Dental Plaque,	of Chewing Sugar-Free and Sugar- " <i>J Dent Res</i> , 72(10):1391-7 (Oct. 1993) –			
134	BIBBY <i>et al.</i> , "Oral Food Cle (Mar. 1986) – Abstract Only;	earance and the pH of Plaque and	1 Saliva," J Am Dent Assoc, 112(3):333-7			
l By	ABELSON et al., "The Effec Abstract Only;	t of Saliva on Plaque pH in Vivo	o," J Dent Res, 60(9):1634-8 (Sep. 1981) –			
136	MILLWARD et al., "Continu Following Consumption of A	ous Monitoring of Salivary Flov cidic Beverages," Caries Res, 32	v Rate and pH at The Surface of the Dentition (1):44-9 (1997) - Abstract Only;			
B	HAYS et al., "Salivary pH W (Oct. 1992) – Abstract Only;	hile Dissolving Vitamin C-Cont	aining Tablets," Am J Dent, 5(5):269-71			
13	NILNER et al., "Effect of a B Acta Odontol Scand, 49(5):26	Buffering Sugar-Free Lozenge on 57-72 (Oct. 1991) - Abstract Onl	Intraoral pH and Electrochemical Action," y;			
1 13		Gingival Crevices and Periodonta):233-8 (1991) - Abstract Only;	al Pockets in Children, Teenagers and			
B	MAGLIS et al., "Determinati ODent Chile, 80(2):70-2 (Aug.	on of Saliva pH in Periodontal D 1989) – Abstract Only;	Disease Patients and a Control Group," Rev			
11 7	1					
13	CHRISTENSEN et al., "Saliv Taste Perception," Physiol Be	vary Changes in Solution pH: A hav, 40(2):221-7 (1987) - Abstr	Source of Individual Differences in Sour act Only;			
1 13,	LAssociation, 118(8):298 (7) (A	August 1989) – Abstract Only;	asis," Journal of the American Dental rch Newsletter, 9(1):6(2) (Jan. 1990) –			
13	Abstract Only;		Ch Newstetter, 9(1).0(2) (Jan. 1990) –			
13,	WALSH, "Do-it-yourself Der Abstract Only;	ntal Rinses. (Your Healthy Smil	e)," <i>Prevention</i> , 47 (6):42(2) (June 1995) –			
13,	, NEWLAND, "Oral Ulcers: K 2 (May 1989);	Keys to Differential and Definitiv	ve Diagnosis," Consultant, 29(5):157(11)			
Br	MOYNIHAN et al., "A Comparison of the Relative Acidogenic Potential of Infant Milk and Soya Infant Formula: A Plaque pH Study," Int J Paediatr Dent, 6(3):177-81 (Sep. 1996) - Abstract Only;					
Bo	THOMSON <i>et al.</i> , "In Vitro <i>a Caries Res</i> , <i>30</i> (6):434-8 (199	and Intra-Oral Investigations into 6) - Abstract Only;	the Cariogenic Potential of Human Milk,"			
131	Nutrition Research Newletter Research, XVI(4):37, 48 (Apr	of John Wiley & Sons, Inc., "Bril 1997);	reast Milk and Dental Caries," Nutrition			
	oquiz 520-1 (NovDec. 1995)	ttle Tooth Decay: A Concern for Abstract Only;	or all Mothers," Pediatr Nurs, 21(6):515-9,			
Examir Signatu			Date Considered 10/10/03			

1		AP.	1 mg	Schie a	
Form PT0	D/SB/08A	E			Complete if Known
			PARECOGA	Applicati n Number	10/051,853
INFORMATION DISCLOSTINGENESS STATEMENT BY APPLICANT			TIPE	Filing Dat	January 17, 2002
STATE	MENI B.	Y APPLIC	CANT	First Named Invent r	Alan E. Kligerman et al
(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		oto on noos		Group Art Unit	1616
(use a	S many She	ets as nece	:55ary)	Examiner Name	Not Yet Assigned
Sheet	4	of	6	Attorney Docket Number	7706-232U1

51	ري	HOLT et al., "The Weaning Diet and Dental Health," Br Dent J, 181(7):254-9 (Oct. 5, 1996) - Abstract Only;
	Cı	TALAN, Newsday Newspaper Article Entitled "Scientists Getting Nearer to Knocking Out Cavities Without Using Fluoride," p. D4 (Jan. 1997);
[]	(3	GRENBY, et al., "Dental Properties of Soft Drinks," Nutrition Research Newsletter, 9(1:7(1) (Jan. 1990);
	C¢	SCHURER-MALY et al., "Smoking and pH Response to H2-Receptor Antagonists," Scand J Gastroenterol, 24(10):1172-8 (Dec. 1989) – Abstract Only;
L	45	ELSON et al., "The Sugar Content And The Ph Of The Smoke Of Cigarette, Cigar And Pipe Tobaccos In Relation To Lung Cancer," Int J Cancer, 9(3):666-675 (1972) - Abstract Only
	4	Single Sheet from Environmental Nutrition, with the caption "Say Cheese," p. 21 (October 1996);
	47	BIRKHED et al., "pH Changes in Human Dental Plaque from Lactose and Milk Before and After Adaptation," Caries Res 27:43-50 (1993) – Abstract Only;
	CS	THOMAS et al., "Astringent Subqualities in Acids," Chem Senses, 20(6):593-600 (December 1995) – Abstract Only;
	G	BASHIR et al., Department of Cariology, School of Dentistry, Karolinska Institutet, Huddinge, Sweden, "Site specificity of citric acid retention after an oral rinse," Caries Res, 29(6):467-9 (1995) - Abstract Only;
	Go	The American Dietetic Association©, Single Information Sheet, "Fig. 1. Definitions of oral health terms," (3/19/97);
L	Cu	News Bites, Single Sheet, "Sports Drinks: Bad for Teeth?" HealthNews, p. 8 (April 15, 1997);
	C ₁ 1	Single page, "Medical Update - Heartburn and Tooth Trouble," Consumer Reports on Health, p. 106, (September 1995);
	41	GRENBY, "Comparison of the Cariostatic Effects of Calcium and Sodium Glycerophosphates in Rats," Helv. Odont. Acta, 17:54, 55 (October 1973);
	C	BROOK et al., "A Clinical Pilot Study of the Effect of Calcium Glycerophosphate," Helv. Odont. Acta, 17:55 (October 1973);
	(₁	Single Sheet, last paragraph, Food Processing, p. 659;
	e	Akademiia Nauk SSSR, Dobladay, 161(1):244-247 (1965);
	(FURIA, ed., "Phosphate Applications in Dairy Products," CRC Handbook of Food Additives, 2 nd Ed., Vol. 11, pps. 660-662 & 666.
H	(<u>(</u>	WEAST, ed.; "Definition of 'Buffer'," CRC Handbook of Chemistry and Physics," 70 th edition, p. F-84
	101	(1989-1990).
<u>Uli</u>	~ ८	"Buffer Solutions," The United States Pharmacopeial /The National Formulary," p. 2049 (1995).

Examiner Signature	Date Considered Collo/03
--------------------	--------------------------



	11	#2	VEENAN 1 "D. G 1 C. Indiana" Communication - 252 (1070)
3	U	y,	KEENAN et al., "Buffered Solutions" General College Chemistry, p. 353 (1976).
1	1	Dr.	"Comparison Chart of Phosphates of Calcium Glycerophosphate," (one page, no date).
Ļ	1	23	"Food Chemicals Codex", 3 rd edition, National Academy Press, p. 574 – 581 (1981).
A	1.	1	BOLOGNA et al., "The Efficacy of Calcium Glycerophosphate in the Prevention of Food-Related Flares
		P4	in Interstitial Cystitis," Urology, 57:6A p.119-120, (2001).
ſ	T		BOWEN, "The Monitoring of Acid Production in Dental Plaque in Monkeys," British Dental Journal, p.
1	1	15	506-508.
ı	\forall		PIANOTTI et al., "Cariostatic Activity of Calcium Glycerophosphate in Hamsters: Topical vs Dietary
ı	- 1	26	Administration," J. Dent Res., 55:6 p. 1092-1096 (1976).
H		200	TU et al. "A Retrospective Analysis of Calcium Glycerophosphate (Prelief) in the Treatment of Food-
1	>	10-	Sensitive Interstitial Cystitis Patients," Association des Urologues du Quebec (No Date One Sheet).
J	_	177	TOAL et al. "Sodium and Calcium Glycerophosphates," British Pharmaceutical Conference, p. 869-
1	\	1	877, (1949).
ŀ		1/2	"Calcium Glycerophophate," Food Chemicals Codex, 4 th Edition, pp. 51-52 and 60-61 (1996)
ŀ		129	"Measurement Procedures," Food Chemicals Codex, 4th Edition (1996).
ŀ		1)10	DVIDAVADY 1 "COL 1 OL 1 L VIDI NO 1 Y 1 A F 1 L COL 1 A
ı		10	BUDAVARI, ed., "Calcium Glycerophosphate," The Merck Index, An Encyclopedia of Chemicals,
ļ		1211	Drugs and Biologicals, 11 th Edition, p. 1675, (1989).
L		DIS	CURTIS, Biology, 2 rd Ed.; Worth Publishers, Inc., p. 597, NY Sixth Printing, February 1978.
- 1	W	_	AARON et al., "Overlapping Conditions Among Patients with Chronic Fatigue Syndrome,
- 1	1	N 2	Fibromyalgia, and Temporomandibular Disorder," Arch. Int. Med. – Online, 2 pages, September 29,
Ĺ	\perp	114	2000.
			PARKER, "If You Have Pelvic Pain," A Gynecologiest's Second Opinion - Online, 6 pages, October 13,
ı			2000.
	Т	יוט	BOLOGNA, et al., "Survey of the Effect of PRELIEF on Food-Related Exacerbation" Analyzed and
	1	וינ	Complied by Paul F. Visintainer, PhD, 20 pages, December 15, 1999.
			JONES, "The Therapeutic Effect of Calcium Glycerophosphate (Prelief [®]) in Interstitial Cystitis," A
		1	Survey of Intestitial Cystitis Support Group (UK) Members, 12 pages, January 2000.
1	1		"Irritable Bowel Syndrome (Spastic Colon)," The Merck Manual of Diagnosis and Therapy – Online,
ſ	4	17.1	Chapter 32, Functional Bowel Disorders, September 29, 2000.
ı	+	71	BEST and TAYLOR's Physiological Basis of Medical Practice, 12th Ed., J.B.West Ed., Williams and
		างไ	Wilkins, pp. 640-674, January 1991.
ŀ	+	<i>\</i> \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	"Irritable Bowel Syndrome – What is Irritable Bowel Syndrome?" NIDDK – National Digestive
		7	Diseases Information Clearinghous (US Govt.) – Online, 6 pages, September 29, 2000.
ŀ	+	רע	FEDOROV, "The Effect of Phosphorus-calcium and Fluorine Compounds on Experimental Dental
- [1	₁	Caries in White Rats," Doklady Academii Nauk SSSR; 137:6 pp. 1481-1484, (1961).
ŀ	+	7 7	Givocal®: Nutritional Ingredient, Carrier of Highly Bioavailable Calcium and Phosphorus; Seppic Inc.,
- [ก	19 pages, September 1997.
ŀ	╀	V1/	ANTANITUS, "A Theory of Cortical Neuron-Astrocyte Interaction," Dept. Pediatrics, Harvard Med.
		ار	
ļ	\perp)Sch. – Online, pp. 1-11, August 3, 2000.
ŀ	. J	/ ~	ADAMS, "Glaxo Irritable-Bowel Treatment Faces FDA Review After Deaths," Wall Street Journal,
4	1	✓ 7) ₁	October 31, 2000.
_		77	

Examiner Signature	9.1	Date Considered 10/00/03

, ,		APR	Š		
Form PTC)/SB/08B	ENT& IR.	.04g		Compl t if Kn wn
		V IR.	ADEMA	Application Number	10/051,853
		DISCLO		Filing Dat	January 17, 2002
SIAIE	MENIR	Y APPLIC	SANI	First Named Inventor	Alan E. Kligerman et al.
/use 2	e many cho	ets as nece	econ)	Group Art Unit	1616
(use a	s many sne	cis as nece	533a1y)	Examiner Name	Not Yet Assigned
Sheet	6	of	6	Attorney Docket Number	7706-232U1

8	wb.	"Potassium Glycerophosphate – Looking for a Superb Energy Enhancer?" Nutrinews – GCI Nutrients – on line, p. 4, October 27, 2000.			
62		NORDSTROM, et al., "Implementation of Intracerebral Microdialysis in Neuro Intensive Care," Microdialysis in Intensive Care –online, University of Lund; Karolinska Institute, Sweden, 4 pages, October 27, 2000.			
+	G	ARAGON, "Experimental Pharmacological Study of the Anti-Spasmodic Action of Sodium-Beta-Glycerophosphate on the Uterus," <i>Anales fac. farm y bioquim</i> , Univ. nacl. Mayor San Marcos 2: 417-429 (1951).			
F	- G	"Irritable Bowel Syndrome" and "Alpha Nutrition Elemental Nutrients Formulas," from website http://www.nutramed.com 5 pages, January 12, 2001.			
	₹ G				
	Y, G	MYERS, "Diagnosing Interstitial Cystitis in Women," Women's Health in Primary Care," 1:2, pp. 133-136, April 2001.			
	16	WHITMORE, et al., "Survey of the Effect of PRELIEF on Food-Related Exacerbation of Interstitial Cystitis Symptoms," 1 page Summary online, February 16, 2001, Philadelphia 1998-99.			
	E,	BOUCRAUT et al., "Evaluation de l'influence du glycerophosphate de calcium sure les cellules corticales (astrocytes et neurones) en culture," Laboratoire d'immunopathologie-Universite d'Aix-Marseilles, 1995.			
	জ	l'acide glycerophosphorique et due calcium sur la survie et la differenciation des neurones de rat en culture," Laboratoire d'immunopathologie-Universite d'Aix-Marseilles.			
"Important Drug Information Product With Drawal-Lotronex® Tablets," 4 pages, November,					
	5~E	"Popular Bowel Drug Banned After Links to Women's Deaths," Atlantic City Press, November 29, 2000.			

Examiner Signature	Date Considered 10/10/07
--------------------	--------------------------

COPY OF PAPERS ORIGINALLY FILE

		9	800	ä. <u> </u>	Maria de la companya della companya	OF WEIVE	
Form PT	O/SB/08A	1		/	Complete if Known	HEOLIVE	Ρ
Manual Phil			erane TRANS	Application Number	10/051,853	000 1 1 2001	1
INFOR	INFORMATION DISCLASSIFICATION STATEMENT BY APPLICANT			Filing Date	January 17, 2002	SEP 1 1 2003	1
SIAIL				First Named Invent r	Alan E. Kligerman et al.		
/,,,,,	se many ch	note ac a	0000001/	Group Art Unit	1616	TECHICIANIA PRISOU	290
(use as many sheets as n cessary)			Cessary)	Examiner Nam	Raymond Henley		
Sheet	1	of	1	Attorney Docket Number	7706-232U1		l

U.S. PATENT DOCUMENTS					
Exr Initials	U.S. Patent Docume	ent	Name of Inventor or Applicant of Cited Document	Date of Publication of Cited Document MM-YYYY	
	Number	Kind Code (if known)			
50	5,504,072		Schmidl et al.	04-1996	
5~	5,719,133		Schmidl et al.	02-1998	
	/				

	FOREIGN PATENT DOCUMENTS							
	Foreign Patent Document				Date of	T ₁		
Exr Initials	Country Code	Number	Kind Code (if known)	Name of Inventor or Applicant of Cited Document	Publication of Cited Document MM-YYYY			
		NA						
						\vdash		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Exr Initials	Include Name of first Author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), volume-issue number(s), page(s), date (in parentheses). If a book, also include publisher and city and/or county where published.	Tı			
		 -			
		<u> </u>			
		L			
		+			
		1			

Examiner		Date	10/1-
Signature	5,00	Considered	1/10/03